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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,897	02/04/2004	Narasimhan Gautam	15060-60	3893

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EXAMINER
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KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1656

NOTIFICATION DATE	DELIVERY MODE
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01/29/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patent@otm.wustl.edu  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/771,897	<b>Applicant(s)</b> GAUTAM ET AL.	
	<b>Examiner</b> CHIH-MIN KAM	<b>Art Unit</b> 1656	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 4,7,9,11,13-15,17,19,20,22-35 and 37-42 is/are pending in the application.
- 4a) Of the above claim(s) 25-30,32-34,41 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4,7,31,35,37,39 and 40 is/are rejected.
- 7) ☒ Claim(s) 9,11,13-15,17,19,20,22-24 and 38 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

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## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 4, 7, 9, 11, 13-15, 17, 19-20, 22-35 and 37-42 are pending.

Applicants' amendment filed October 14, 2009 is acknowledged. Applicants' response has been fully considered. Claims 25-30, 32-34 and 41-42 are non-elected inventions and are withdrawn from consideration in this Office Action. Therefore, claims 4, 7, 9, 11, 13-15, 17, 19, 20, 22-24, 31, 35 and 37-40 are examined.

### **Withdrawn Claim Rejections - 35 USC § 112**

2. The previous rejection of claims 9, 11, 13-15, 17, 19, 20, 22-24 and 43-45 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment to the claims, applicants' cancellation of the claim, and applicants' response at page 9 in the amendment filed October 14, 2009.

### ***Maintained Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 7, 31, 37 and 39-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claim 7 is indefinite as to how to screen candidate agonists and antagonists when the method merely recites the step of exposing an intact living cell containing the receptors and the

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G protein biosensor to the candidate agonists and antagonists without indicating the step of measuring FRET or BRET signals.

*Response to Arguments*

Applicants indicate claims 7, 9, 11, 15, 17, 19, 37, 39 and 40 have been amended to address these rejections, and claims 43-45 have been cancelled. Thus, these rejections should be withdrawn (page 9 of the response).

Applicants' response has been considered. Regarding claims 9, 11, 15, 17 and 19, the arguments are persuasive, the rejection of these claims is withdrawn. However, regarding claims 7 and 39-40, the arguments are not persuasive because the claims still lack an essential step in the process as indicated in the rejection.

5. Claim 31 is indefinite because the claim recites "said method comprising operating an intact living cell where the mammalian G-protein biosensor of claim 4 as well as receptors are expressed using a baculovirus vector and obtaining a FRET profile", it is not clear how the steps of expression using intact living cells and obtaining a FRET profile are correlated with the method of classification of candidate agonists, antagonists and inverse agonists.

9. Claims 37, 39 and 40 are indefinite because the claims lack essential steps in the claimed methods. For example, the claim merely recites the step of exposing an intact live biosensor cell containing a receptor and the G-protein biosensor of claim 4 with a candidate molecule, it is not clear how to classify the candidate therapeutic molecule as agonists, antagonists or inverse agonists.

***Claim Rejections-Obviousness Type Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 4 and 35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 45-46 of co-pending application 10/914,049 (based on the amendment filed 9/9/2009). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 4 and 35 in the instant application disclose a functional G protein biosensor comprising a mammalian  $\alpha$  subunit comprising a first amino acid sequence encoding at least one of a first fluorescent or a luminescent protein, and a mammalian  $\beta\gamma$  subunit complex, wherein the  $\beta$  subunit comprises a second amino acid sequence encoding at least one of a second fluorescent or luminescent protein and the  $\gamma$  subunit comprise a third amino acid sequence encoding at least one of a third fluorescent and or luminescent protein, wherein said first, second and third fluorescent or luminescent proteins are at least FRET or BRET capable. This is obvious variation in view of claims 1-3 and 45-46 of the co-pending application which disclose a functional biosensor comprising heterotrimeric G protein alpha, translocatable beta and gamma subunits wherein both beta and gamma subunits are tagged with a fluorescent protein or a luminescent protein. Both sets of claims cite directed to a functional biosensor comprising

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heterotrimeric G protein alpha, translocatable beta and gamma subunits wherein both beta and gamma subunits are tagged with a fluorescent protein or a luminescent protein. Thus, claims 4 and 35 in present application and claims 1-3 and 45-46 in the co-pending application are obvious variations of a functional biosensor comprising heterotrimeric G protein alpha, translocatable beta and gamma subunits wherein both beta and gamma subunits are tagged with a fluorescent protein or a luminescent protein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

*Response to Arguments*

While applicants have filed a terminal disclaimer on March 26, 2009, this terminal disclaimer has not been approved because the attorney is not of record. Thus, the rejection is maintained.

***Claim Objections***

7. Claims 9, 11, 13-15, 17, 19, 20, 22-24 and 38 are objected to because the claims are dependent from a rejected claim.

***Conclusion***

8. Claims 4, 7, 31, 35, 37 and 39-40 are rejected; and claims 9, 11, 13-15, 17, 19, 20, 22-24 and 38 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached at 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/

Primary Examiner, Art Unit 1656

CMK

January 25, 2010